# Optimal keratoplasty for the correction of presbyopia and hypermetropia

Submission date	Recruitment status No longer recruiting	Prospectively registered		
04/03/2017		☐ Protocol		
Registration date 14/03/2017	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
15/02/2022	Eve Diseases			

#### Plain English summary of protocol

Background and study aims

Presbyopia is a condition associated with aging of the eye that leads to s progressively worsening ability to focus clearly on close objects. In a younger person, the lens is soft and flexible so it can easily reshape the lens to focus on close and distant objects. With age, the lens becomes harder so it is unable to reshape as easily. Hyperopia, also known as farsightedness, is another forma of presbyopia which makes it difficult for people to focus on things that are close. Optimal keratoplasty is a new form of laser eye treatment to treat presbyopia. It works by remodeling the shape of the cornea (transparent layer forming the front of the eye) to help sharpen distance vision and near vision. The aim of this study is to investigate the safety and effectiveness of optimal keratoplasty in correcting hyperopia (long-sightedness) and presbyopia.

Who can participate?

Adults aged 40 years and over who have hyperopia and presbyopia

What does the study involve?

All participants receive optimal keratoplasty, which involves having a special laser applied to their eyes while they are lying down. The procedure takes around 10-15 minutes altogether. Before the procedure and then one hour, one day, one week and one, three and six months after the procedure, participants have an eye test in order to find out if there has been any improvement to their vision.

What are the possible benefits and risks of participating?

Participants may benefit from an improvement to their eyesight. There is a small risk that some participants may experience minor vision problems for a short time after the procedure, such as glare (light entering the eye and interfering with vision) and halos (bright circles that surround a light source).

Where is the study run from? Istituto Europeo di Microchirurgia Oculare (Italy)

When is the study starting and how long is it expected to run for? June 2014 to June 2016

Who is funding the study? Istituto Europeo di Microchirurgia Oculare (Italy)

Who is the main contact? Professor Paolo Lanzetta

# **Contact information**

### Type(s)

Public

#### Contact name

Prof Paolo Lanzetta

#### **ORCID ID**

https://orcid.org/0000-0003-3746-141X

#### Contact details

Istituto Europeo di Microchirurgia Oculare via Fiducio 8 Udine Italy 33100

# Additional identifiers

#### Protocol serial number

I-2014A27

# Study information

#### Scientific Title

In patients with presbyopia and hypermetropia, do optimal keratoplasty improve near and distance visual acuity?

# **Study objectives**

Optimal keratoplasty is safe and effective for the correction of hyperopia and presbyopia.

# Ethics approval required

Old ethics approval format

## Ethics approval(s)

Istituto Europeo di Microchirurgia Oculare (IEMO) Institutional Review Board, 22/03/2014, ref: I-2014A27

## Study design

Single-centre single-arm non-randomised study

# Primary study design

#### Interventional

#### Study type(s)

Quality of life

#### Health condition(s) or problem(s) studied

Presbyopia and hypermetropia

#### Interventions

All patients undergo laser irradiation of the corneal tissue using the NTK Optimal Keratoplasty (Opti-K) System.

While the patient is lying in a supine position, an output beam is directed onto the cornea in a symmetrical square ring pattern (6 and 7.2 mm diameter), so that the corneal epithelium is protected from thermal damage with a sapphire application window/suction ring. Thereafter, laser is applied at 1.93  $\mu$ m wavelength. The laser is typically operated with a total delivered power of 0.80-1.28 W for a period of 150 ms. The duration of the entire procedure is approximately 10-15 minutes.

Patients are evaluated at baseline, 1 hour, 1 day, 1 week, 1 month, 3, and 6 months after treatment. The duration of a visit is about an hour. Baseline and follow-up examinations include measurement of uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), CDVA, manifest refraction, corrected near visual acuity (CNVA), presbyopic add, corneal optical coherence tomography (OCT), corneal pachymetry, slit lamp examination of the anterior segment, and dilated fundus examination.

### Intervention Type

Procedure/Surgery

# Primary outcome(s)

Mean uncorrected near visual acuity is measured by ETDRS charts and standardized procedures at baseline and 6 months.

# Key secondary outcome(s))

Uncorrected distance visual acuity in hypemetropic/presbyopic eyes is measured by ETDRS charts and standardized procedures at baseline and 6 months.

# Completion date

01/06/2016

# **Eligibility**

### Key inclusion criteria

- 1. Aged 40 years and over
- 2. Low to moderate hypermetropia (manifest refraction: sphere between +1 to +2.5 D, absolute cylinder  $\leq$ 1 D) or presbyopia (with presbyopic adds between +1D to +2.75 D)
- 3. Documented stable refraction
- 4. Corrected distance visual acuity (CDVA) of 33 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or better

#### Participant type(s)

#### **Patient**

### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

# Key exclusion criteria

- 1. Nystagmus
- 2. Corneal diameter ≤9 mm
- 3. Central corneal thickness ≤500 µm
- 4. Dry eye disease
- 5. Severe blepharitis
- 6. Residual, recurrent or active corneal disease or abnormality

#### Date of first enrolment

01/07/2014

#### Date of final enrolment

01/05/2016

# Locations

#### Countries of recruitment

Italy

# Study participating centre Istituto Europeo di Microchirurgia Oculare

via Fiducio 8 Udine Italy 33100

# Sponsor information

#### Organisation

Istituto Europeo di Microchirurgia Oculare

#### **ROR**

https://ror.org/02t9kcf24

# Funder(s)

## Funder type

Other

#### Funder Name

Istituto Europeo di Microchirurgia Oculare

# **Results and Publications**

## Individual participant data (IPD) sharing plan

Participant level data are stored as medical charts at the center. Charts are anonymised with a numeric code. Patients signed an informed consent allowing data storage.

## IPD sharing plan summary

Stored in repository

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/04/2017	15/02/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes